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510(k) Summary
K081042
BSD Medical Corporation
MicroThermX®-100 Microwave Ablation System

1. **Preparation Date:** August 26, 2008

2. **Submitted By:** SEP - 3 2008

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Contact/Prepared by:

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3. **Device Identification**

Trade Name	MicroThermX®-100 Microwave Ablation System and Accessories
Common Name	Microwave Ablation System
Classification Name	**21CFR§878.4400** System, Ablation, Microwave and Accessories

4. **Predicate Device(s)**

K833158, K950301, K011676, K031556, K032702, K040279, K050223, K053535

5. **Device Description**

The MicroThermX®-100 Microwave Ablation System (MTX-100) delivers microwave energy for coagulation (ablation) of soft tissue. The delivery of microwave energy is controlled by time and power parameters set by the operator. The system consists of a mobile generator, generator cart, microwave applicators, Over-The-Needle (OTN) catheters for applicator insertion, and optional temperature sensors and temperature sensor positioning tubes. The mobile generator is comprised of a computer, microwave generator, thermistor-based temperature monitoring system, and thermal calibration well. The operator interface is via a touchscreen monitor.

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6. Intended Use

The MicroThermX®-100 Microwave Ablation System (MTX-100) delivers microwave energy for coagulation (ablation) of soft tissue. The system is not intended for use in cardiac procedures.

The MTX-100 microwave applicators, which are inserted using the provided OTN catheters, may be use in open surgical as well as percutaneous ablation procedures. Optional temperature sensors may be used to monitor tissue temperatures.

7. Summary of Technological Characteristics in relation to Predicate Device(s)

The BSD MTX-100 System combines the characteristics of the predicate devices into one convenient system. The intended use, technology employed, principles of operation, basic design, and materials of construction are substantially equivalent to one, or more, of the predicate devices.

8. Assessment of Performance Data used to Justify Substantial Equivalence Claim

Verification and Validation testing that was successfully completed included:

- A biocompatibility safety assessment in accordance with FDA Memo G95-1 and ISO 10993-1;
- Evaluation of the safety and performance of the MTX-100 System, in accordance with all, or part, of the following standards:
  - **UL 60601-1, ed. 1**
  - **IEC 60601-1-2, ed. 2.1**
  - **IEC 60601-2-2, ed. 4**
  - **IEC 60601-2-6, ed. 1**
  - **CISPR 11**;
- Verification of accessory performance in accordance with in-house protocols and relevant standards; and
- Usability testing.

No clinical data were necessary in order to support the safety and efficacy of the device.

9. Conclusion

Based on the acceptable safety and performance of the subject MTX-100 System and the similarities between the subject System and the predicate devices, BSD Medical asserts that the MTX-100 System and Accessories are substantially equivalent to the predicate devices and are safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 3 2008

BSD Medical Corporation
% Phil Triolo and Associates
Phil Triolo, PhD
148 S. 1200 E.
Salt Lake City, Utah 84102-1643

Re: K081042
Trade/Device Name: MicroThermX®-100 Microwave Ablation System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: NEY
Dated: August 13, 2008
Received: August 13, 2008

Dear Dr. Triolo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K081042

Indications for Use

510(k) Number (if known): 081042

Device Name: BSD Medical MicroThermX®-100 Microwave Ablation System

Indications For Use:

The MicroThermX®-100 Microwave Ablation System (MTX-100) delivers microwave energy for coagulation (ablation) of soft tissue. The system is not intended for use in cardiac procedures.

The MTX-100 microwave applicators, which are inserted using the provided OTN catheters, may be used in open surgical as well as percutaneous ablation procedures. Optional temperature sensors may be used to monitor tissue temperatures.

Prescription Use ____X____ AND/OR Over-The-Counter Use _____ (Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K081042